

REMARKS

Claims 44 - 80 are presently pending in this application. This request for reconsideration is based on the incomplete response by the examiner to Applicant's previous response. It is also noted that the Applicant filed its previous response on December 4, 2008 but failed to receive a timely Office Action to this response. The Office Action was not mailed out until over 7 month's delay despite repeated telephone calls to the examiner and to the Supervisory Patent Examiner, most of which were not returned.

Applicant incorporates the previous remarks from Applicant's previous Request for Reconsideration mailed out on December 4, 2008. In addition, Applicant requests further clarification on the following issues:

- 1) The Examiner's failure to address numerous points that were brought forth in the December 4, 2008 response. Does this mean that the Patent Office is conceding these issues, as addressed below, or are they simply being ignored? If these issues are being conceded, then the claims should be allowed. If these issues were being ignored, then these issues must be addressed in order for them to be taken up on appeal.
- 2) Failure to appreciate the critical limitation of the thickness of the Applicant's invention as opposed to the prior art.
- 3) Failure to appreciate the critical limitation of the strength of adhesiveness of the Applicant's invention as opposed to the prior art.
- 4) Failure to appreciate the critical limitation of the ratio of elongation of the Applicant's invention.
- 5) Failure to appreciate the critical limitation of an orthotic device having less than 15% elongation when subjected to a 25 lb/inch tensile load.

6) Failure to appreciate that there simply is no motivation to drastically alter the prior devices as suggested by the examiner to achieve Applicant's claimed inventions.

1) Failure to address issues raised in Applicant's December 4, 2008 response

In the response filed by Applicant on December 4, 2008, Applicant raised the following issues that were not failed the Office Action mailed on June 25, 2009:

a) Orthotic device vs. a foot protector

Applicant's claimed invention includes the limitation of an orthotic device. Applicant provided the correct definition of orthotic as being a support, brace or splint used to support, align, prevent or correct the function of movable parts of the body. This definition clearly excludes the protector of Burgess. Yet Examiner, without any support whatsoever, refers to Burgess as disclosing an orthotic device. This is wholly improper. Clearly, the resilient foot protector of Burgess is simply a cushioning device to protect the sole of the foot from conditions on a walking surface. See column 2, lines 28 – 35. The Examiner has failed to provide any evidence whatsoever that would classify the foot protector of Burgess as an orthotic device that is able to support, align, prevent or correct the function of movable parts of the body. The examiner is requested to either supply credible and convincing evidence as to why the cushioned foot protector of Burgess is an orthotic or remove this characterization and allow the claims.

b) Size and Shape

Applicant's claimed invention includes the limitation of having a shape matching less than the entire outline of a sole of a wearer's foot to which the device is to be applied and sized to cover only a portion of the wearer's sole. Burgess on the other hand is required to having a shape generally matching a shape of a sole of a foot and generally corresponding in size to the foot. Burgess specifically states that it's foot protector can only be slightly smaller than the sole of the foot, unlike the Applicant's claimed invention, in order to protect the foot, as is the stated purpose of the device. Burgess teaches away from having a shape matching less than the entire outline of a sole of a wearer's foot for to do so would defeat the purpose of the foot protector of Burgess. As set forth in MPEP 2143.01

Changes in mere size or shape in some circumstances may be considered obvious combinations or modification, but would not be considered obvious in the case where doing so would destroy the functioning of the reference, or make it unsatisfactory for its intended purpose. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."

Clearly in this instance, to render the device of Burgess to make it less than the entire sole of the wearer's foot would render it unsatisfactory from protecting the foot from walking conditions. The examiner is requested to provide credible and convincing evidence as to why this modification would not render the prior art invention unsatisfactory for its intended purpose, or withdraw the rejection and allow the claims.

c) Objective Evidence of Nonobviousness

The Applicant provided in the December 4, 2008 response objective evidence of nonobviousness. This evidence was ignored and the examiner failed to provide any reason for not considering this evidence. According to MPEP 2145:

Office personnel should consider all rebuttal arguments and evidence presented by applicants. See, e.g., *Soni*, 54 F.3d at 750, 34 USPQ2d at 1687 (error not to consider evidence presented in the specification). *Cf.*, *In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996) (error not to consider factual evidence submitted to counter a **35 U.S.C. 112** rejection); *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992) (Office personnel should consider declarations from those skilled in the art praising the claimed invention and opining that the art teaches away from the invention.); *Piasecki*, 745 F.2d at 1472, 223 USPQ at 788 ("[Rebuttal evidence] may relate to any of the *Graham* factors including the so-called secondary considerations.").

Further:

Rebuttal evidence may include evidence of "secondary considerations," such as "commercial success, long felt but unsolved needs, [and] failure of others." *Graham v. John Deere Co.*, 383 U.S. at 17, 148 USPQ at 467. See also, e.g., *In re Piasecki*, 745 F.2d 1468, 1473, 223 USPQ 785, 788 (Fed. Cir. 1984) (commercial success)

Further, according to MPEP 716.01 (a):

"The Court of Appeals for the Federal Circuit stated in *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 USPQ 871, 879 (Fed. Cir. 1983) that "evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." Such evidence

might give light to circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or unobviousness, such evidence may have relevancy. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *In re Palmer*, 451 F.2d 1100, 172 USPQ 126 (CCPA 1971); *In re Fielder*, 471 F.2d 640, 176 USPQ 300 (CCPA 1973). The *Graham v. John Deere* pronouncements on the relevance of commercial success, etc. to a determination of obviousness were not negated in *Sakraida v. Ag Pro*, 425 U.S. 273, 189 USPQ 449 (1979) or *Anderson's-Black Rock Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969), where reliance was placed upon *A&P Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 87 USPQ 303 (1950). See *Dann v. Johnston*, 425 U.S. 219, 226 n.4, 189 USPQ 257, 261 n.4 (1976).”

The Applicant, in the December 4, 2008 response, provided strong evidence of secondary consideration including satisfying a long felt need. This evidence also provides a strong nexus between the satisfying of a long felt need and the claim limitations.

Satisfying a Long Felt Need

The present invention as set forth in the claims solves a long felt need by providing a solution not previously provided by other attempts.

- 1) The treatment of plantar fasciitis has long been a problem. See Exhibits A – D for representative articles from the Mayo Clinic and from other reputable sources.
- 2) This problem has not been solved by others. See Exhibits A – D, the treatments for this problem involve: a) rest; b) stretching; c) thick insoles; d) anti-inflammatory medication. None of the prior art cited by the examiner or found in the literature discuss using a non-stretching adhesive sole member adhered to the sole of the foot.
- 3) The presently claimed invention solves this problem. See Declaration of Dr. Delamos, Exhibit E. The declaration clearly provides a nexus between the success of the problem (plantar fasciitis) and the unique features of the claimed invention (stretch resistant sole portion with a strong adhesive layer that restricts the extension and stretching of the outer skin tissue).

This objective evidence is dispositive of the nonobviousness of the presently claimed invention. A key limitation found in the claims of a “stretch-resistant sole member sufficiently stretch-resistant to restrict extension and stretching of an outer skin tissue on the sole of a foot, when adhered thereto” provides the nexus between the ability of the product of the claimed invention to satisfy the long felt need of treating plantar fasciitis as set forth in the declaration of Dr. Delamos.

The examiner is requested to either provide credible and convincing evidence to rebut this evidence or to withdraw the rejection and allow the claims.

d) Failure to address the limitation of woven micro-fiber

Claims 55, 73 and 77 include the limitation of a woven micro-fiber. The Office Action failed to address this limitation. None of the cited prior art references disclose this feature. The examiner is requested to either provide credible and convincing evidence as to why this limitation, which is not disclosed or suggested in the prior art, would be obvious, or withdraw the rejection to these claims.

e) Failure to address the limitation of not using a resilient cushion layer.

Claim 75 includes the specific limitation of a sole support that does not include a resilient cushion layer. Since Burgess explicitly requires that it's foot protector is a cushioned layer, it specifically teaches away from this limitation. The device of Burgess would not function as intended if it did not include a cushion layer. As stated earlier, a modification of a prior art device can not be considered obvious if it alters the functionality of the prior art device.

The examiner is requested to either provide credible and convincing evidence why it would be obvious to destroy the functionality of Burgess by adding this limitation or to withdraw the rejection to these claims.

The above issues need to be addressed for either withdrawing the rejection of the claims or for purposes of addressing these issue upon appeal.

2) Failure to appreciate the critical limitation of the thickness of the Applicant's invention as opposed to the prior art.

The Office Action indicated that the critical limitation of the thickness of Applicant's claimed invention being .074 mm or less thick is found in the disclosure in Burgess of the thickness being about 1 mm thick. This is a difference of 26% between the thickness of the two devices, with the 1 mm thickness in Burgess being the absolute lower end of the device of Burgess performing it's function, while the .074 is at the upper end of Applicant's range. Burgess explicitly states at column 3, lines 13 – 32, that "First, a thickness of about 1 mm to

about 5 results in a foot protector 100 that has enough resilience, or cushion effect, to provide comfort to the foot of the wearer, but which is lightweight enough that it can be held to the foot 200 with an adhesive having relatively low tack, or stickiness.” To make it any less than 1 mm would remove the cushion effect from the wearer. Burgess teaches away from a thickness less than 1 mm, and certainly one that is 26% less thick.

3) Failure to appreciate the critical limitation of the strength of adhesiveness of the Applicant’s invention as opposed to the prior art.

Applicant specifically includes limitations in the claims that require a strong adhesive that will minimize tensile stresses on the plantar fascia. Burgess specifically discloses that a low tack, or low strength adhesive is necessary in order to prevent discomfort to the wearer. Burgess likens the strength of the adhesive in the disclosed device as similar to that of a “Post-it” note. Burgess discloses, column 3, lines 1 – 8, that “Preferably, the tack adhesive used in the tack adhesive layer 120 is sticky enough to reliably hold the foot protector 100 against the foot 200, *but is not so sticky that it causes difficulty or discomfort in removing the foot protector 100 from the sole of the foot 200. The easier it is to remove the foot protector 100 from the sole of the foot 200, the more the wearer can experience the comfort level of a conventional slipper.*” Clearly this teaches away from the use of a strong adhesive. Thus, to one skilled in the art, Burgess only discloses an adhesive no stronger than that used in Post-It notes and Band-Aids and certainly no stronger than would cause difficulty in removing the foot protector. *Burgess teaches using the lowest possible strength adhesive that will allow the foot protector to merely remain on the foot.*

Applicant, on the other hand, requires that the adhesive be high strength, in order to minimize tensile forces on the plantar fascia. There is nothing in Burgess, or any of the prior art references cited, that disclose, suggest, or in any way teaches to use a high strength adhesive that will require tensile forces on the plantar fascia to be shared with the outer skin and with the orthotic device. This sharing of the forces creates considerable restriction to the flexing of the foot and flattening of the arches of the foot which is absolutely opposite of the teaching of Burgess. Burgess teaches the comfort of a slipper without limiting foot movement. Further Burgess teaches it may be applied over a stocking or sock, indicated it is not intended for the orthotic purpose of sharing tension with the plantar fascia. There is nothing in Burgess, or any of

the prior art references that would suggest using a high strength adhesive to one skilled in the art. The only suggestion of doing so is in the Applicant's application.

4) Failure to appreciate the critical limitation of the ratio of elongation of the Applicant's invention.

The Applicant specifically requires the limitation of a ratio of elongation to tensile strength of the orthotic device to be less than .9. The examiner cites Desnoyers as disclosing a pressure sensitive tape that has a ratio of elongation to tensile strength ratio of at least about 3 to 1. Desnoyers discloses a tape for bundling objects together. Desnoyers fails to disclose anywhere in the patent that the ratio of elongation to tensile strength is less than .9. Desnoyers discloses a ratio of elongation to tensile strength to be 3 to 1 which would be 3/1 or 3, not less than .9 (or a >333% difference). **There is no disclosure in any of the prior art references of using an orthotic device having a ratio of elongation to tensile strength of less than .9.**

5) Failure to appreciate the critical limitation of an orthotic device having less than 15% elongation when subjected to a 25 lb tensile load.

Applicant specifically includes the limitation of an orthotic device having less than 15% elongation when subjected to a 25 lb/inch tensile load. This reduces the tensile forces on the plantar fascia. The Office Action cites Huddleston as teaching this limitation and that it would be merely obvious to combine the tape of Huddleston with the other references to arrive at the presently claimed invention. Huddleston teaches a metallic tape for use with rigid fiberglass air ducts that would clearly be unsuitable for use as a comfortable foot protector and most certainly as an orthotic device. The metallic tape of Huddleston would be damaging to the skin and absolutely unsuitable for use with the foot. One skilled in the art would most certainly not use this metallic tape intended for use with rigid fiberglass air ducts as an orthotic device. Furthermore, Huddleston while addressing the 25lb/inch tensile load, does not indicate the critical limitation of having less than 15% elongation when subject to a 25lb load. Finally, as stated in the applicants specification the plantar fascia is "effectively inelastic", in order to effectively share load with the fascia to limit or prevent damage in it the adhered device would need have similar "effectively inelastic" characteristics, which is taught away from in Burgess.

6) Failure to appreciate that there simply is no motivation to drastically alter the prior devices as suggested by the examiner to achieve Applicant's claimed inventions.

The examiner has attempted to combine a foot protector having a cushioned layer with a low tack adhesive intended to provide comfort to a wearer's foot with a protective device for protecting a foot from rough terrain, hot sands and pavement having a thick cushion to allegedly render Applicant's claimed invention of an orthotic device for minimizing tensile forces on the plantar fascia. Additional references ranging from metallic tapes for repairing rigid fiberglass air ducts, ankle braces, to tape for bundling objects together. None of the references cited by the examiner even mention the phrase "plantar fascia", much less function to minimize tensile forces on it. The examiner has simply used a shopping list created from Applicant's invention and found disparate references that mention one of the limitations and throw these together without any suggestion in any of the references to do so.

The United States Supreme Court recently set forth the test for finding obviousness in combining references. As the Court found in the 2007 KSR decision:

For a prima facie case of obviousness to be established there must be "an apparent reason to combine the known elements in the fashion claimed." KSR Int'l. Co. v. Teleflex Inc., 127 S.Ct. 1727, 1740-41 (2007).

That prima facie case must be clear and convincing. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). MPEP 706.02(j).

The motivation relied upon by the Examiner must not come solely from the description of the Applicant's invention in their specification. If it does, the Examiner used impermissible hindsight when rejecting the claims. See *W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540, 1553, (Fed. Cir. 1983); *In re Rothermel*, 276 F.2d 393, 396 (CCPA 1960).

Here the examiner has failed to find any apparent reason to combine the known elements in the fashion as Applicant has claimed.

None of the references, taken singly or combination with one another disclose, suggest or teach an orthotic device that has a thin sole member that is stretch-resistant and that has an adhesive layer that will prevent the outer skin to which it is adhered from extending to prevent excessive stresses on the plantar fascia. Burgess and Holden specifically teach away from such a device in that their foot protectors enable the foot to move without restriction.

These claims are believed to be in condition for allowance. Applicant respectfully request that the rejection be reconsidered and that a timely Notice of Allowance be issued in this case.

The Examiner is respectfully requested to telephone the undersigned if further discussions would advance the prosecution of this application.

Respectfully submitted,

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